

# PSJ3

# Exhibit 17

## DRAFT 2008 GOALS

**EMPLOYEE:** Anita T. Ducca  
**POSITION:** Senior Director, Regulatory Affairs & Healthcare Policy  
**FOR PERIOD:** January 1, 2008 – December 31, 2008

### JOB ELEMENTS:

1. Strive to identify opportunities to incorporate of HDMA's position(s) on federal regulatory initiatives affecting the wholesale distribution industry. Work toward creating changes in federal regulatory requirements reflective of HDMA member's policy positions. 45%

### **SPECIFIC GOALS**

- Work toward identifying critical federal regulatory and related initiatives impacting the distribution industry, analyzing their impact, and toward development of strategies to support HDMA policies.
- DEA - Launch an initiative to proactively define DEA regulatory issues, develop policy positions and advocate such positions on behalf of HDMA's members. Includes, but is not limited to:
  - Suspicious Orders requirements and interpretations of implementing regulations
  - In-Transit Losses
  - Requirements for obtaining regulated sellers' self-certification numbers
  - Methadone
  - Iodine registration requirements
- Risk Management and Related Initiatives – Proactively identify and define FDA Risk Management and related regulatory issues, develop policy positions and advocate such positions on behalf of HDMA's members. Includes, but is not limited to:
  - Risk Management
  - Medication Guides
  - Electronic PIs
  - iPLEDGE
- As needed, strive to conduct appropriate follow-up interactions to further support written comments and oral testimony on the NDC rule particular regarding repackaging and definitions of relabeling.
- PDMA:
  - Work with FDA staff to further clarify remaining questions and to seek revisions with respect to FDA's guidances (particularly the Q & A

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guidance issued in Nov. 2006) that are comparable to HDMA's prioritized positions.

- Strive to develop and advocate regulatory policies and positions designed to implement legislation directing FDA to develop standards for unique identifiers.
- Strive to develop and advocate HDMA policies and positions on FDA efforts to implement anticipated uniform (electronic) pedigree/track and trace legislation.
- Strive to enhance familiarity with, and conduct outreach to, key agency staff and stakeholders. Includes outreach among, senior and political appointee and other regulatory agency staff including staff of the Centers for Medicare and Medicaid Services (CMS), the Food and Drug Administration (FDA) and the Drug Enforcement Administration (DEA). Also includes staff of Trade Associations with interests in common to HDMA and its members (e.g., NACDS, NCPA, CHPA, etc.)
- Participate in additional HDMA committee meetings and seek to develop policies and communications regarding regulatory initiatives that require Government and Public Policy Council (GPPC) and the Government Affairs Committee (GAC) review/acceptance. Includes, but is not limited to, recommending regulatory policies and strategies for Committee consideration.

**2. Lead HDMA Regulatory Affairs Committee (RAC) and Regulatory Affairs and Healthcare Policy budget process activities, and participate in HDMA educational programs and HDMA committee management. 20%**

**SPECIFIC GOALS**

- Act as staff to the RAC. Strive to establish appropriate agenda, identify priorities for RAC consideration, and work with the committee to develop policies consistent with industry goals.
- Strive to identify at least one educational session for the Distribution Management Conference, solicit a speaker and work with the speaker to develop the session.
- Work towards establishing a federal Regulatory Affairs budget that adequately funds agreed-to priorities.
- Strive to administer of the Regulatory Affairs budget without exceeding budget allocations.

**3. Work towards enhancing the Policy Development Program. 10%**

**SPECIFIC GOALS**

- Work towards identification of issues critical to HDMA membership suitable for in-depth evaluation and analyses.

- Upon identification and agreement with GA Senior V.P., work towards identification of analytical mechanisms and/or expertise to address these issues within allocated budget. Determine suitable end products for use by HDMA and its members. Manage the analysis of identified issues and appropriate communication of final products.
- As priorities permit, act as principal liaison to the HDMA Healthcare Foundation on behalf of Government Affairs. Share information about upcoming GA activities as well as laws impacting HDMA members. Strive to collaborate with Foundation staff on economic or other industry analyses as appropriate.

**4. Supervise Manager, Regulatory Affairs including efforts to advance and support the HDMA/Regulatory Affairs objectives. 25%**

**SPECIFIC GOALS**

- Provide oversight and guidance on designing strategies to ensure effectiveness of HDMA's advocacy efforts and on appropriate internal and external HDMA teamwork to address these issues.
- Provide guidance on updating and implementing the HDMA AMP Action Plan to address proposed and final AMP rule and on further developing the RSP (or other) alternative(s).
- Provide guidance on monitoring CMS regulatory initiatives, such as the Medicare Part B (ASP) activities and taking appropriate action if needed.
- Provide guidance on monitoring federal regulatory agency efforts to ensure distributor role in pandemic response efforts.
- Strive to continue development of the skills and performance of the Manager, Regulatory Affairs. Includes expanding the Manager's knowledge and responsibilities regarding federal regulatory initiatives beyond CMS to include FDA and DEA.

**SUMMARY OF GOALS/WEIGHTS**

**Strive to identify opportunities to incorporate of HDMA's position(s) on federal regulatory initiatives affecting the wholesale distribution industry. Work toward creating changes in federal regulatory requirements reflective of HDMA member's policy positions. 45%**

**Lead HDMA Regulatory Affairs Committee (RAC) and Regulatory Affairs and Healthcare Policy budget process activities, and participate in HDMA educational programs and HDMA committee management. 20%**

**Work towards enhancing the Policy Development Program. 10%**

**Supervise Manager, Regulatory Affairs including efforts to advance and support the HDMA/Regulatory Affairs objectives. 25%**

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